



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Certificate of Analysis (Manidipine)

Issue Date: 20 FEB 2026 Quality Release Date: 20 FEB 2026

### Product Name

Manidipine 马尼地平

### Product Information

Product Number MAN-20260220  
Batch Number MAN-SH2026022001  
Brand SIGALD  
CAS Number 89226-50-6  
MDL Number MFCD00867626  
Formula  $C_{35}H_{38}N_4O_6$   
Formula Weight 602.70 g/mol

### Test Results

Test	Specification (USP 45 & ChP 2025)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (on dry basis)	$\geq 99.0\%$	99.8%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 0.5\%$	0.07%	%	HPLC (USP 45)
Single Impurity	$\leq 0.1\%$	0.01%	%	HPLC (USP 45)
Loss on Drying	$\leq 0.5\%$	0.04%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	$\leq 0.1\%$	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	$\leq 10$ ppm	0.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 2$ ppm	0.05 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	$\leq 0.5$ EU/ $\mu$ g	0.02 EU/ $\mu$ g	EU/ $\mu$ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	124 ~ 128 °C	126.3 °C	°C	Melting Point Apparatus
pH Value (0.1% methanol solution, 25 °C)	6.0 ~ 8.0	7.2	-	Digital pH Meter
Optical Rotation (25 °C, c=1 in CHCl <sub>3</sub> )	+42° ~ +48°	+45.1°	°	Polarimetry

### Certification

This batch of product has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **Chinese Pharmacopoeia (2025 Edition)** for pharmaceutical raw materials. All test results meet the specified pharmacopoeial requirements, and the product is qualified for use in the production of clinical antihypertensive pharmaceutical preparations.